REMARKS

Claims 26-37 and 39-45 are the currently pending claims. Claims 39-45 have been withdrawn from consideration. Claims 26-29 are amended, and claim 38 is canceled. No new matter is added. The amendments to the claims were made solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to any objection or rejection of any claim. Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Support for the amending language "candidate bioactive peptide" may be found in the specification on page 5, lines 5-14. Support for the amending language "peptide of from 4 to 100 amino acids in length" may be found on page 5, lines 15-22.

Claims 26-38 have been rejected under 35 U.S.C. 112, first paragraph. The Office Action states that the specification does not provide adequate written description of the claimed method where the randomized candidate nucleic acid is a target molecule. The Office Action further states that the specification fails to describe a random library with a presentation sequence.

Applicants respectfully submit that the presently claimed invention meets the requirements of 35 U.S.C. 112, first paragraph.

As discussed in the specification of the present application (see page 35, line 13, ff), either the bioactive agent or the bioactive nucleic acid encoding it is used to identify target molecules, i.e. the molecules with which the bioactive agent interacts. In a preferred embodiment, the bioactive agent is used to pull out target molecules. For example, as outlined herein, if the target molecules are proteins, the use of epitope tags or purification sequences can allow the purification of primary target molecules via biochemical means. Alternatively, the peptide, when expressed in bacteria and purified, can be used as a probe against a bacterial cDNA expression library made from mRNA of the target cell type. Or, peptides can be used as "bait" in either yeast or mammalian two or three hybrid systems. Synthetically prepared labeled peptide can be used to screen a cDNA library expressed in bacteriophage for those cDNAs, which bind the peptide.

One of skill in the art would readily understand that the target molecule is not a part of the randomized nucleic acid, but is the "molecule with which the bioactive agent interacts".

The claims have been amended to clarify the nature of the presentation structure, which is a polypeptide structure encoded by the nucleic acid sequences. The specification (for example, see page 6, lines 20-34), provides a detailed description of such structures, which are sequences that, when fused to candidate bioactive agents, causes the candidate agents to assume a conformationally

restricted form. Proteins interact with each other largely through conformationally constrained domains. The presentation of peptides in conformationally constrained structures benefit both the later generation of pharmaceuticals and likely lead to higher affinity interactions of the peptide with the target protein.

Applicants respectfully submit that the present application provides adequate written description for a target molecule, and for the use of a library comprising a presentation structure. In view of the above amendments and remarks, withdrawal of the rejection is requested.

Claims 26-38 have been rejected under 35 U.S.C. 112, second paragraph. The claims have been rewritten to clarify the identification of a target molecule in both the method steps and the preamble. The relationship between the nucleic acid, and the peptide which it encodes, has been clarified. As described above, the target molecule is a molecule that interacts with the bioactive peptide.

The reference to a cyclic peptide in the Office Action is unclear, as the present claims do not recite a cyclic peptide.

Claim 27 has been amended to recite the identification of the target. Claim 38 has been canceled. The recitation of a presentation structure in Claim 29 has been clarified.

Applicants respectfully submit that Claim 28 properly limits the base claim. While Claim 26 recites the identification of a target, Claim 28 further specifies that the target is isolated.

In view of the above amendments and remarks, Applicants respectfully submit that the present claims meet the requirements of 35 U.S.C. 112, second paragraph. Withdrawal of the rejection is requested.

Claims 26-38 have been rejected under 35 U.S.C. 101 for statutory double patenting over claims 1-13 of U.S. Patent no. 6,153,380.

In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? 35 U.S.C. 101 prevents two patents from issuing on the same invention, where "same invention" means identical subject matter. *Miller v. Eagle Mfg.* Co., 151 U.S. 186 (1984); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert,* 245 F.2d 467, 114 USPQ 330 (CCPA 1957). The pending claims and the claims of the '380 patent are not identical. The present claims specifically recite the identification of a target sequence. Such elements are not present in the claims of the '380 patent and therefore are not statutory double patenting. Withdrawal of the rejection is requested.

Claims 26-38 are provisionally rejected under 35 U.S.C. 101 for statutory double patenting over claims 1 and 8-13 of published application 2002/0146710. Applicants respectfully submit that a provisional rejection of this type is properly addressed by allowance of one application, in the absence of other outstanding rejections, at which time a determination of double-patenting can be made based on the issued claims. Withdrawal of the rejection is requested.

Claims 26-28 and 30-31 have been rejected under 35 U.S.C. 102(e) as being anticipated by Jensen *et al.* (2001/0053523). Applicants respectfully submit that Jensen *et al.* is not available as prior art to the present application. The PCT filing date for Jensen *et al.* is May 31, 1996. As quoted in the Office Action, 35 U.S.C. 102(e) provides for an application filed under the treaty defined in section 351(a) to be a reference. Priority documents filed under national law outside of the United States do not meet this requirement. Therefore, the earliest date on which Jensen can be available as a reference is the PCT filing date; i.e. May 31, 1996.

The present application claims priority to USSN 08/589,911, which was filed on January 23, 1996. Therefore Jensen *et al.* is not a reference. Withdrawal of the rejection is requested.

Claims 23-28 have been rejected under 35 U.S.C. 103(a) as unpatentable over Jensen in view of either Luzzago or Dower *et al.* As discussed above, Jensen *et al.* is not available as a reference. The secondary references do not make obvious the presently claimed invention.

Luzzago *et al.* describes a library of peptides inserted into the N-terminal region of a bacteriophage coat protein, with two cysteine residues flanking the insert. The Luzzago *et al.* library was not screened for an intracellular effect, but was selected for binding to antibodies. The present claims are distinguished from the prior art by screening for intracellular transdominant activity.

Dower *et al.* similarly utilizes a library of peptides attached to a bacteriophage structural protein, which peptides are screened for binding to an extracellular receptor. The present claims are distinguished from the prior art by screening for intracellular transdominant activity.

Applicants respectfully submit that the present claims meet the requirements of 35 U.S.C. 103. Withdrawal of the rejection is requested.

CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number RIGL-004CON4.

Respectfully submitted,
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Date: May 13, 2003

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